



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Docket No. PHUS-58

1616  
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JUN 11 2002  
TECH CENTER 1600/2900

In re application of:  
Vergez, Juan et al.

Group Art Unit: 1616

Serial No.: 09/992,488

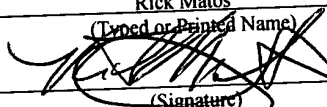
Examiner: N/A

Filed: November 6, 2001

For: Pharmaceutical Compositions  
Containing Oxybutynin

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

<p><u>CERTIFICATE OF MAILING</u> <u>UNDER 37 C.F.R. § 1.8(a)</u></p> <p>I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, DC 20231 on June 6, 2002.</p> <p>Rick Matos (Typed or Printed Name)</p> <p> (Signature)</p>
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### INFORMATION DISCLOSURE STATEMENT

The following sections are submitted for this Information Disclosure Statement:

1. \_\_\_\_ Preliminary Statements
2. X FORM PTO - 1449
3. \_\_\_\_ Statement As To Information Not Found in Patents or Publications
4. \_\_\_\_ Identification Of Prior Application In Which Information Was Cited And For Which No Copies Are Submitted Or Need Be Submitted
5. \_\_\_\_ Cumulative Patents or Publications
6. \_\_\_\_ Translation(s) of Non-English Language Documents
7. \_\_\_\_ Concise Explanation of Non-English Language Listed Information Items
8. X Copies of Listed Information Items Accompanying This Statement
9. X Identification of Person(s) Making This Information Disclosure Statement

Section 1. Preliminary Statements

Applicant submits herewith patents, publications or other information which may be material to the examination of this application and for which there may be a duty to disclose in accordance with 37 CFR 1.56.

The filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made (37 CFR 1.56(g)), or as an admission that the information cited is, or is considered to be, material to patentability.

The filing of this Information Disclosure Statement shall not be construed as an admission against interest in any manner.

Section 2. FORM PTO - 1449

Form PTO - 1449 (2 pages) is enclosed herewith.

Section 3. Statement As To Information Not Found In Patents Or Publications (Information not listed in PTO 1449)

Section 4. Identification Of Prior Application In Which Information Was Cited And for Which No Copies Are Submitted Or Need Be Submitted

This application relies, under 35 U.S.C. 120, on the earlier filing date of prior application S/N \_\_\_\_\_, filed on \_\_\_\_\_.

Section 5. Cumulative Patents or Publications

\_\_\_\_\_ is cumulative of the following patents or publications listed on Form PTO 1449:

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In accordance with 37 CFR 1.98(c) a copy of only \_\_\_\_\_ is being submitted with this information disclosure statement.

Section 6. Translation(s) of Non-English Language Documents

- Submitted herewith is an English translation of the following foreign language patents, publications or information or of those portions of those patents, publications or information considered to be material.
- No English language translations of the foreign language patents, publications or information or parts thereof are readily available, except for those listed above.
- The following foreign language documents submitted are believed to be the equivalent or substantial equivalent of the English language documents identified below, which are also submitted herewith.

Section 7. Concise Explanation of Non-English Language Listed Information Items

Section 8. Copies of Listed Information Items Accompanying This Statement

Legible copies of all items listed in Form PTO-1449 accompany this information statement.

— Exception(s) to above

— Items in prior application from which an earlier filing date is claimed for this application as identified in Section 4.

— Cumulative patents or publications identified in Section 5.

Section 9. Identification of Person(s) Making This INFORMATION DISCLOSURE STATEMENT

The person making this statement is

(a) — the inventor(s) who signs below

\_\_\_\_\_  
Signature of Inventor

\_\_\_\_\_  
Typed name of inventor

(b) X the agent who signs below on the basis of:

— information supplied by the inventor(s)

— information supplied by an individual associated with the filing and prosecution of this application (37 CFR 1.56(c))

X information in the agent's file

It is respectfully requested that the references identified in this Information Disclosure Statement be considered by the Examiner, be made a part of the official record, and be cited in the issued patent.

Date: 6/6/2  
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Respectfully submitted,



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Please type a plus sign (+) inside this box →

PTO/SB/08A (10-96)

Approved for use through 10/31/99. OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO

JUN 11 2002

Complete if Known

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

Application Number 09/992,488  
Filing Date November 6, 2001  
First Name and Inventor Vergez, J. A.  
Group Art Unit 1616  
Examiner Name  
Attorney Docket Number PHUS-58

TECH CENTER 1600 2900  
JUN 13 2002

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## U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	A1	4,111,202		Theeuwes, F.	09/05/1978	
	A2	4,309,996		Theeuwes, F.	01/12/1982	
	A3	4,327,725		Cortese et al.	05/04/1982	
	A4	4,449,983		Cortese et al.	05/22/1984	
	A5	4,455,143		Theeuwes, F.	06/19/1984	
	A6	4,612,008		Wong et al.	09/16/1986	
	A7	4,624,847		Ayer et al.	11/25/1986	
	A8	4,662,880		Hamel et al.	05/05/1987	
	A9	4,627,971		Ayer, A.	12/09/1986	
	A10	4,681,583		Urquhart et al.	07/21/1987	
	A11	4,723,957		Magruder et al.	02/09/1988	
	A12	4,765,989		Wong et al.	08/23/1988	
	A13	4,814,181		Jordan et al.	03/21/1989	
	A14	4,863,456		Stephens et al.	09/05/1989	
	A15	4,867,969		Magruder et al.	09/19/1989	
	A16	4,909,474		Theeuwes et al.	02/27/1990	
	A17	4,915,954		Ayer et al.	04/10/1990	
	A18	4,931,285		Edgren et al.	06/05/1990	
	A19	4,960,416		Stephens et al.	10/02/1990	
	A20	4,971,790		Magruder et al.	11/20/1990	
	A21	5,006,346		Edgren et al.	04/09/1991	
	A22	5,082,668		Wong et al.	01/21/1992	
	A23	5,160,743		Edgren et al.	11/03/1992	
	A24	5,160,744		Jao et al.	11/03/1992	
	A25	5,190,765		Jao et al.	03/02/1993	
	A26	5,208,037		Wright et al.	05/04/1993	
	A27	5,252,338		Jao et al.	10/12/1993	
	A28	5,399,359		Baichwal, A.	03/21/1995	
	A29	5,543,155		Fekete et al.	08/06/1996	
	A30	5,674,895		Guittard et al.	10/07/1997	
	A31	5,788,987		Busetti et al.	08/04/1998	
	A32	5,866,164		Kuczynski et al.	02/02/1999	
	A33	5,840,754		Guittard et al.	11/24/1998	
	A34	5,912,268		Guittard et al.	06/15/1999	
	A35	6,106,864		Dolan et al.	08/22/2000	

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number.

<sup>2</sup> See attached Kinds of U.S. Patent Documents.

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PTO/SB/08A (10-96)

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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 2

## **Complete if Known**

Applicati n Number 09/992,488  
Filing Dat N v mber 6, 2001  
First Named Inv ntor V rgez, J. A.  
Gr up Art Unit 1616  
Examiner Name  
Attorney Docket Number PHUS-58

## **FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>2</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	B1	WIPO	96/12477		Rantala, P.	05/02/1996		
	B2	WIPO	97/18814		Macrae et al.	05/29/1997		
	B3	WIPO	00/12069		Nilvebrant et al.	03/09/2000		
	B4	WIPO	00/19997		Guittard et al.	04/13/2000		
	B5	Japan	2,646,170		Nippon Hoechst Marion Roussel Ltd.	08/25/1997		
	B6	Japan	2,665,858		Nippon Hoechst Marion Roussel Ltd.	10/22/1997		

## **OTHER- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		DMOCHOWSKI, R. et al., Advancements in Pharmacologic Management of the Overactive Bladder, Urology, December 2000, Volume 56 (Supplement 6A), 41-49.	
		APPELL, R.A. et al., Clinical Evaluation of a Sustained-Release Form of Oxybutynin (Ditropan SR) for the Treatment of Detrusor Hyperreflexia in Neuropathic Patients, Urodynamics Society Symposium Abstracts, 1990, 228.	
		SIRKIA, T. et al., use of Hydrophilic Polymers to Control Drug Release from Press-Coated Oxybutynin Hydrochloride Tablets, S.T.P. Pharmacia Sci.,1993, 21, 3-8.	
		NILSSON, C. G. et al., Comparison of a 10-mg Controlled Release Oxybutynin Tablet with a 5-mg Oxybutynin Tablet in Urge Incontinent Patients, 1997, 16:533-542.	